10 510(K) SUMMARY

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the PICA Catheter.

10.1 Sponsor/Applicant Name and Address

Penumbra Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

10.2 Sponsor Contact Information

Seth A. Schulman
Director, Regulatory Affairs
Phone: 510-748-3223
FAX: 510-217-6414
email: seth.schulman@penumbrainc.com

10.3 Date of Preparation of 510(k) Summary

December 22, 2009

10.4 Device Trade or Proprietary Name

PICA™ Catheter

10.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

10.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Penumbra System Reperfusion Catheter	Penumbra, Inc Alameda, CA	K072718 & K090752
Neuron™ Intracranial Access System	Penumbra, Inc Alameda, CA	K070970, K082290 & K083125

10.7 Device Description:

The PICA Catheter is a variable stiffness catheter with an outer diameter of 0.056in, has a catheter shaft reinforced with a stainless steel coil, and has a radiopaque markerband on the distal end. It is available with an inner diameter of 0.041in and in various lengths. The PICA Catheter has a PTFE-lined lumen, which is coil re-enforced, flexible, and hydrophilically coated. The PICA Catheter is inserted through a guide catheter or vascular sheath, provides access to the target site and once in place, provides a reinforcing conduit for other intravascular devices. The device is provided sterile and includes a rotating hemostasis valve and tip shaping mandrel. The PICA Catheter will be available in various configurations to allow physician ease of device tracking to the target site

10.8 Intended Use:

The PICA™ Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

10.9 Summary of Non-clinical Data:

Biocompatibility tests conducted for the PICA Catheter were selected in accordance with ISO-10993 -1 guidelines (Biological Evaluation of Medical Devices) for external communicating devices contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

Non-clinical testing found the PICA Catheter to be biocompatible and non-pyrogenic. The physical, mechanical and performance testing of the subject PICA Catheter demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Penumbra, Inc.
c/o Seth A. Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

JAN 15 2010

Re: K093970
Trade/Device Name: PICA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (2)
Product Code: LIT, DQY
Dated: December 22, 2009
Received: December 23, 2009

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 STATEMENT OF INDICATION FOR USE

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K093970

Device Name: PICA™ Catheter

Indications for Use:

The PICA™ Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Prescription Use ___X___ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093970

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